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IFW 1642 1304 seq

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PTO/SB/21 (08-00)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	08/949,904
Filing Date	15 October 1997
First Named Inventor	LaVallie
Group Art Unit	1642
Examiner Name	Ungar
Total Number of Pages in This Submission	
Attorney Docket Number	31896-52000 (GI5288B)

ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [x] Amendment / Reply
  - [ ] After Final
  - [x] Affidavits/declaration(s)
- [x] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
  - [ ] 1449
  - [ ] References (4)
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [x] Power of Attorney, Revocation Change of Correspondence Address
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Raymond Van Dyke
Signature	
Date	May 12, 2004

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FEE TRANSMITTAL FOR FY 2004

Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)1,130.00

Complete if Known	
Application Number	08/949,904
Filing Date	October 15, 1997
First Named Inventor	LaVallie et al.
Examiner Name	Ungar
Art Unit	1642
Attorney Docket No.	31896-52000

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 19-2380

Deposit Account Name: Nixon Peabody LLP

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below		Fee Paid
Total Claims	-20** =		X		=	0
Independent Claims	-3** =		X		=	0
Multiple Dependent			X		=	0

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	950.00
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive – unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)1,130.00

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/949,904	10/15/1997	EDWARD R. LAVALLIE	GI-5288B	8744

22852 7590 11/12/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/12/2003

42

Please find below and/or attached an Office communication concerning this application or proceeding.

Docketed 11/14/03 Attorney
Case 268
Due Date
Action
By

PTO-90C (Rev. 10/03)

TRANSF. TO WYETH 11/14

Office Action Summary	Application No. 08/949,904	Applicant(s) Lavallie et al
	Examiner Ungar	Art Unit 1642

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 18, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-19, 21-24, 26, 27, 30,-33* is/are pending in the application.

4a) Of the above, claim(s) *1-17, 21, 24, 26, 27, and 30-32* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18, 19, 22, 23, and 33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *41*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 18, 2003 (Paper Nos. 39, 40 and 41) have been entered.

2. The Amendment filed September 18, 2003 (Paper No. 40) in response to the Office Action of May 23, 2003 (Paper No. 37) is acknowledged and has been entered. Previously pending claim 20 and 29 have been canceled, claim 18 has been amended and new claim 33 has been added. Claims 18-19, 22, 23, 33 are currently being examined.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

4. Claims 18-19, 22, 23 remain rejected under 35 USC 101 and newly added claim 33 is rejected under 35 USC 101 for the reasons previously set forth in Paper No. 37, Section 5, pages 2-5.

Applicant argues that the presence of murine SDF-5 mRNA in a variety of tissues does not detract from the utility of SDF-5 in increasing cartilage formation when it is combined with BMP2 as demonstrated in Example 7 of the application and one utility of the invention is in SDF-5's ability to work additively with BMP-2 to increase cartilage formation a described in Example 7, of the application. This is

a specific, substantial and credible utility. The argument has been considered but has not been found persuasive because Example 7 does not provide evidence that SDF-5 increases cartilage formation in combination with BMP2 for the reasons of record. Example 7 is drawn to an *in vitro* assay that demonstrates that treatment, of cells in culture, with the combination of BMP-2 and SDF-5 resulted in a significant decrease in markers for bone and hypertrophic cartilage and that markers for cartilage were increased. The specification clearly differentiates between the "significant" results for bone and hypertrophic cartilage and the simple "increase" for cartilage markers. Further, contrary to Applicant's arguments, the Example does not demonstrate any increase in cartilage formation. Finally, as drawn to the *in vitro*, cell culture assay, for the reasons of record, no one of skill in the art would believe that the invention could be used as suggested based only on the cell culture information provided in the specification.

Applicant further argues that to demonstrate utility of an invention, it is not necessary to describe the mechanism of cartilage formation, be it through blocking Wnt activity or any other mechanism. Applicant argues that MPEP states that if n asserted utility is credible to a person of ordinary skill, a rejection under 35 USC 101, utility should not be imposed. The argument has been considered but has not been found persuasive because the suggested uses do not appear to be credible for the reasons of record. Further, for the reasons of record, rejection under 35 USC 101, utility is proper.

Applicant further argues that the specification identifies the biological activity of SDF-5 in formation of cartilage and have correlated it to the treatment of cartilage

disorders. The argument has been considered but has not been found persuasive, the only biological activity demonstrated for SDF-5 is an activity of "increasing" cartilage markers in a cell line in combination with BMP-2 in an *in vitro* assay. For the reasons disclosed previously and above, there is no teaching that the "increase" is in any way significant, there is no teaching that the *in vitro* treatment led to cartilage formation and finally, the cell culture data cannot be extrapolated to the *in vivo* condition. Given the above, the claimed invention does not have utility for the reasons of record.

The *in vitro* data disclosed in Example 7 is accepted in the art as being correlated with *in vivo* activity. Applicant points to Rosen et al, Gori et al, Kearns et al. The argument has been considered but has not been found persuasive because a review of Rosen et al reveals that it is drawn to a review the MLB13MYC-clone 14 cell line used in Example 7. Rosen et al reveal that the clone-14 cell line is an early skeletal progenitor cell clone with no constitutive expression of chondroblast or osteoblast phenotype genes before BMP treatment. Upon treatment with BMP-2, the cell line expresses morphologic and biochemical features of chondroblasts and then osteoblasts (p. 1761, col 2). The reference also reviews MBL13MYC-clone 17 which is a prechondroblastlike cell line which constitutively express low levels of one or more of the biochemical and molecular markers associated with chondroblast-like cells before BMP-2 addition (p. 1761, col 1). The reference further states that the established cell lines are capable of expressing chondroblast-like phenotypes *in vitro* (p. 1764, col 1). The reference further states that "We also begin to address the relationship between osteoprogenitor and chondropogenitor

cells (apparently the clone-17 and clone 14 cell lines) as it **may** (emphasis added) relate to endochondral bone formation", thus as of November 9, 2001 it is clear that the cell lines used in Rosen et al were not fully characterized (p. 1760, col 1). Given the proviso "may", Rosen et al very specifically stated that the information gained from the cell lines could not be directly applied to the *in vivo* situation and clearly infer that further research was required to establish a "real world use" for the information acquired. A review of Gori et al revealed the characterization of BIG-3 that is induced as clone-17 acquires osteoblastic features in response to BMP-2 wherein it was found that BIG-3 accelerates the program of osteoblastic differentiation in stably transfected MC3T3E1 cells (p. 46515, col 1). A review of Kearns et al reveals that the reference is drawn to characterization of a novel protein kinase that impairs osteoblast differentiation *in vitro* wherein the kinase was identified during BMP-2-induced differentiation of the clone-17 cell line to an osteoblastic phenotype (p. 42213, col 1). The reference concludes that "This novel kinase is likely to play an important regulatory role in attenuating the program of osteoblast differentiation (p. 42213, col 1). Although Applicant argues that the cell line used in Example 7 is accepted in the art as being correlated with *in vivo* activity, nothing is the cited references suggests or states that the information gained can be directly extrapolated to, or reliably correlated with *in vivo* activity. Further, although Rosen et al state that some growth factors, known to be regulators of the cartilage cell phenotype, potentiated the expression of chondroblast properties in BMP-2 treated cells (para bridging cols 1 and 2 of p.1766), Rosen et al do not suggest that this potentiation is in any way associated with an *in vivo* function.

Further, even if this potentiation were to be found to in some way be associated with *in vivo* function, SDF-5 does not appear to be a growth factor that is a regulator of cartilage cell phenotype because Example 7 clearly demonstrates that SDF-5 alone has no effect on the cartilage cell phenotype. For the reasons set forth previously and above, given the nature of the data presented and the state of the art, the claimed invention lacks utility.

Applicant further argues that MPEP 2107.01 state that under appropriate circumstances the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. The argument has been considered but has not been found persuasive because Applicant has neglected to disclose "appropriate circumstances" and has thus mischaracterized the teachings of the MPEP. A review of MPEP 2107.01 reveals that Applicant's reference is to a section of the MPEP wherein the active ingredient in a composition that was a structural analog to a known anticancer agent was disclosed. The Applicant in that case provided evidence showing that the calmed analogs had the same general pharmaceutical activity as the known anticancer agents. The fact pattern disclosed in the instant application is very different than the fact pattern disclosed in the MPEP. SDF-5 polypeptide is a novel polypeptide with unknown pharmaceutical activity and without any disclosed structural analogy to any known modulator of BMP-2 activity or any known activity in cartilage formation.

In particular MPEP 2107.01 clearly states that a "substantial utility" defines a "real world" use.

> Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. ..... the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;.....

The instant fact pattern demonstrates that additional work must be done in order to establish a "real world" use for the instantly claimed invention and for the reasons set forth previously and above, the claimed invention does not have utility.

Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

5. Claim 20 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 37, Section 6, page 6)

The rejection of claim 20 under 35 CFR 112, first paragraph is maintained because applicant did not distinctly and specifically point out the supposed errors in the rejection.

6. Claims 18-19, 22, 23 remain rejected under 35 USC 112, first paragraph and new claim 33 is rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 37, Section 7, page 6.

Applicant argues that Dermer et al supports the patentability of the instant invention because of the teaching that "new drugs are selected for human trials because they kill tumor cell lines in the laboratory", thus supporting the fact that *in*

vitro testing provides enablement for new drugs and the fact that Dermer does not agree with this method is irrelevant to the patentability of the current invention. The article is merely an editorial opinion and the subject matter of cancer is not relevant to SDF-5 or any protein related to SDF-5. The argument has been considered but has not been found persuasive because a review of the Dermer statement reveals that Applicant is mischaracterizing the intent of the statements in the reference. Dermer clearly discloses that the use of cell lines is responsible for the continued ineffectiveness of chemotherapeutics against cancer. Dermer does not support the enablement of the instant invention based on *in vitro*, cell line assay. Further, the editorial article demonstrates the state of the art at the time the invention was made. Further, although the reference is drawn to the use of cancer cell lines, the information in the reference is clearly relevant to any type of cell line *in vitro* assay because the reference clearly teaches that cell lines do not mimic conditions in the human body. Further, the reference teaches that cells in culture take an evolutionary-type step that enables the new line to thrive in its artificial environment. This is true not only for cancer cell lines but for all cell lines. The cultured cells are transformed and are in reality a new life form on Earth, neither human nor animal. Finally, contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years. Given this teaching, it is clear that for the reasons set forth previously and above, the assay disclosed in Example 7 does not correlate with *in vivo* activity.

Applicant further argues that Freshney does not speak to the understanding of those skilled in the art in 1997. Although Freshney recognizes the differences

Serial No: 08/949,904

Art Unit: 1642

between *in vitro* and *in vivo* models he states that as long as the limits of the model are appreciated, *in vivo* models can become a valuable tool. The arguments have been considered but have not been found persuasive because none of the examples presented in the specification are *in vivo* models. Applicant is invited to submit 1997 references that establish that the clone-14 cell line cells used in the Example 7 are identical to the primary parent cells from which they are derived, that they have not been transformed in any way, that no evolutionary-type step has occurred that enabled them to thrive in the artificial environment, that the conditions in the petri dish are identical to those found in the human body and that the information obtained from the cell line can be directly extrapolated to the *in vivo* condition. This is especially important in view of the teaching of Rosen et al, *Supra,* that the information found in the cell line assays "may" relate to the *in vivo* condition.

Applicant further argues that the model disclosed in Example 7 is well known to correlate with *in vivo* activity and points again to Rosen et al. Applicant further points to Gori et al and Kearns et al to disclose that the model is acceptable to those of skill in the art. The argument has been considered but has not been found persuasive, the Rosen et al reference is not commensurate in scope with the claimed invention, the Rosen et al reference deals with the well characterized effects of BMP-2 and not with the effects of novel and uncharacterized polypeptides upon BMP-2 function *in vivo*. Further, as drawn to the Gori et al and Kearns et al references, nothing in the cited references suggests or states that the information gained can be directly extrapolated to, or reliably correlated with *in vivo* activity.

Serial No: 08/949,904

Art Unit: 1642

Applicant further argues that Examiner's argument that the invention is not enabled based on the inability to show that the sequence binds to the Wnt binding domain is not well taken. Enablement does not require that the mechanism by which the frazzled protein causes the formation of chondrocytes and/or cartilage tissue, it is enough that it does cause the formation or chondrocytes and/or cartilage tissue. Applicant points to case law and MPEP 2164. The argument has been considered but has not been found persuasive. The enablement rejection, in Paper No. 28, which included disclosure of lack of Wnt binding consensus sequence in either of claimed sequences, was drawn to Examiners review of the specification and the disclosed "uses" of the claimed polypeptides. Applicant clearly included the putative Wnt binding function in the specification in order support the utility and enablement of the invention. Examiner's rejection disclosed why those uses were not enabled. Applicant, in Paper No. 32, submitted an attachment in which Applicant suggested that the attachment was indicative of the ability of human SDF-5 protein to regulate the binding of Wnt proteins, thus supporting the enablement of the claimed invention based on the mechanism of Wnt binding. This was not found persuasive for the reasons of record. Although information drawn to a mechanism of action is clearly not necessary for the enablement of a claimed invention, for the reasons set forth previously and above, the invention is not enabled and the information drawn to a putative Wnt binding function, wherein neither of claimed polypeptides includes a Wnt binding consensus sequence does not provide enablement for the claimed invention.

Serial No: 08/949,904

Art Unit: 1642

Applicant's arguments have not been found persuasive and the rejection is maintained.

7. No claims allowed

8. All other objections and rejections recited in Paper No. 37 are hereby withdrawn.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
November 11, 2003